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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,616	05/08/2002	Y. Tom Tang	PF-0662 USN	6963

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FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/889,616	TANG ET AL.	
	Examiner	Art Unit	
	David J Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,8,15 and 28-30* is/are pending in the application.

4a) Of the above claim(s) *29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,8,15,28 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/19/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] Claims 1-2, 8, 15, and 28-30 are pending in the application.

[2] Applicants' amendment to the claims, filed November 19, 2004, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

[3] Receipt of an information disclosure statement (IDS), filed November 19, 2004, is acknowledged.

[4] Applicants' arguments filed November 19, 2004 have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

[5] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Lack of Unity

[6] Claim 29 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

[7] Claims 1-2, 8, 15, and 28, and 30 are being examined on the merits.

Information Disclosure Statement

[8] All references cited on the IDS filed November 19, 2004 have been considered by the examiner. A copy of the IDS is attached to the instant Office action.

Claim Rejections - 35 USC § 112, Second Paragraph

[9] Claims 1, 8, 15, 28, and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is necessitated by amendment.

[a] Claim 1 (claims 8, 15, 28, and 30 dependent therefrom) is indefinite in the recitation of "nucleic acid binding activity." The specification discloses the polypeptides of the invention are "nucleic acid binding proteins" (p. 1, lines 2-3). However, as evidenced by Table 2, the term "nucleic acid binding activity" encompasses a diverse array of polypeptide activities, including proteins having DNA polymerase activity, DNA helicase activity, and numerous other distinct nucleic acid binding activities. As such, it is unclear as to the scope of polypeptides encompassed by the claim. It is suggested that applicants clarify the meaning of the term "nucleic acid binding activity."

[b] Claim 30 is indefinite in the recitation of "a cell proliferative disorder" as it is unclear as to the scope of disorders that are intended as being encompassed by the term. It is suggested that applicants clearly and specifically identify those disorders that are intended to be encompassed by the term "a cell proliferative disorder."

[c] Claim 30 recites the limitation "said compound." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 101

[10] The utility rejection of claims 1-2, 8, 15, 28, and 30 under 35 U.S.C. 101 and the corresponding enablement rejection of claims 1-2, 8, 15, 28, and 30 under 35 U.S.C. 112, first paragraph are maintained for the reasons of record as set forth at items [11] and [12] of the Office action mailed August 19, 2004, the reasons of record as set forth at items [14] and [15] of the Office action mailed April 21, 2004 and for the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the specification describes the claimed protein as a zinc finger transcription factor protein and that "mutations in transcription factors contribute to oncogenesis...due to the role of transcription factors in the expression of genes." Applicants argue SEQ ID NO:19 has 99% identity to a polypeptide, referred to as "SNAI1" and annotated as a zinc finger transcription factor, whose sequence was published after the filing of the instant application. Applicants argue the post-filed references of Cano et al., Poser et al., and Okubo et al. (all cited in the IDS filed November 19, 2004) demonstrate the specific role the claimed polypeptide plays in several cell proliferative disorders and that the specification states that the claimed protein may be used to treat or prevent a disorder associated with either decreased or increased expression of the claimed polypeptide including melonoma and cancers of the breast and gastrointestinal tract. Applicants argue that in view of these teachings, one would not need to determine the diseases that can be treated or prevented using the claimed polypeptide. Applicants' argument is not found persuasive.

There is no dispute that the specification appears to identify the protein of SEQ ID NO:19 as a "C2H2-type zinc finger protein" (p. 63). However, beyond this teaching,

the specification fails to provide any specific guidance for using the protein of SEQ ID NO:19 for any diagnostic or therapeutic application. It should be noted that, while the polypeptide sequence of SNAI1 is nearly identical to SEQ ID NO:19, SEQ ID NO:19 is *not* SNAI1 and should not be confused as such. In this case, it is just as likely that SEQ ID NO:19 is an inactive, *i.e.,* non-functional, mutant of SNAI1 as there is no evidence of record that SEQ ID NO:19 has the asserted activity of a zinc finger protein. Also, it is noted that the amino acid sequence of SNAI1 and corresponding annotations were not available at the time of the invention. Even assuming *arguendo* the sequence of SNAI1 and its corresponding annotations were available at the time of the invention, the teachings of Cano et al., Poser et al., and Okubo et al. were not and MPEP 2164.05(a) makes clear that the specification must be enabling as of the filing date of the application. Even assuming *arguendo* the teachings of Cano et al., Poser et al., and Okubo et al. were publicly available at the time of the invention, these teachings fail to provide the guidance that is necessary for a skilled artisan to diagnose or treat any disease or disorder without further experimentation. In this case, the specification clearly fails to provide the necessary specific guidance for a skilled artisan to diagnose, treat, or prevent a disease or disorder, including a "cell proliferative disorder" as recited in claim 30. The specification merely provides generic teachings that are meant to apply to any of the claimed nucleic acids or polypeptides. There is no specific guidance for using the claimed polypeptide for treatment or diagnosis and, as such, further experimentation is required to practice this utility. Applicants are invited to point out how a skilled artisan, using the claimed invention and the instant specification/prior art of

record for guidance, can diagnose or treat a specific disease or disorder. At least for the reasons of record and the reasons stated above, the asserted utility is not substantial as the specification must teach a skilled artisan how to use what is claimed and not merely provide a blueprint for further experimentation in order for an artisan to identify a use for the claimed invention. See Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). As stated in Brenner v. Manson, 383 U.S. 519 535-536, 148 USPQ 689, 696 (1966), "[a] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." Thus, the claimed invention is not supported by a specific and substantial asserted utility and the examiner knows of no well-established use for the claimed invention.

Claim Rejections - 35 USC § 112, First Paragraph

[11] The written description rejection of claims 1, 8, 15, 28, and 30 is maintained for the reasons of record as set forth at items [13] and [14] of the Office action mailed August 19, 2004, the reasons of record as set forth at item [17] of the Office action mailed April 21, 2004, and for the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the specification "describes relevant structural features of the claimed protein," citing Table 2 of the specification. Applicants argue claim 1 part (b) has been amended to recite both structural and functional features and claim 1 part (c) has been amended to recite immunogenic fragments of a polypeptide having the sequence of SEQ ID NO:19. Applicants' argument is not found persuasive.

As stated in a previous Office action the species encompassed by the genus of claimed or recited polypeptides are widely variant and the single representative disclosed species of SEQ ID NO:19 fails to represent all members of the claimed genus. Regarding claim 1 part (b), while the genus is limited to those polypeptides that are 90% identical to SEQ ID NO:19 and having "nucleic acid binding activity," it is noted that even this genus is widely variant with respect to the numerous "nucleic acid binding" activities that are encompassed by the term as evidenced by applicants' disclosure (pp. 1-2 and the numerous "nucleic acid binding" functions that are disclosed in Table 2. Also, regarding claim 1 part (c), it is noted that the recited immunogenic fragment is of "a polypeptide having... SEQ ID NO:19." These polypeptides include any polypeptide that has SEQ ID NO:19 and any additional amino acids at the N- or C-terminus of SEQ ID NO:19. As such, the immunogenic fragment can encompass any amino acid sequence as long as the fragment comprises "at least 30 contiguous amino acids of SEQ ID NO:19." In this case, the genus encompasses species that are widely variant in structure and function and the single representative species of SEQ ID NO:19 fails to describe all polypeptides encompassed by the genus of the claim. At least for the reasons of record and the reasons stated above, the single representative species of SEQ ID NO:19 fails to describe all species of polypeptides as encompassed by the claims.

[12] Even if applicant demonstrates a specific and substantial or well-established utility for SEQ ID NO:19, the following rejection is maintained. The scope of enablement rejection of claims 1, 8, 15, 28, and 30 is maintained for the reasons of record as set

forth at items [15] and [16] of the Office action mailed August 19, 2004, the reasons of record as set forth at item [17] of the Office action mailed April 21, 2004 and for the reasons stated below.

RESPONSE TO ARGUMENT: Regarding how to make variant proteins, applicants argue the specification discloses potential phosphorylation sites and "signature sequences" of SEQ ID NO:19 and that a skilled artisan would know to "maintain those domains of SEQ ID NO:19" as shown in Table 2. Applicants argue Table 2 provides the guidance necessary for a skilled artisan to alter SEQ ID NO:19 with an expectation of retaining nucleic acid binding activity. Applicants attempt to discount the teachings of Branden et al. and Witkowski et al. by asserting that the teachings of Branden et al. are "only general" and the teachings of Witkowski et al. do not address a nucleic acid binding protein. Applicants' argument is not found persuasive.

It should be noted that there is no evidence of record that SEQ ID NO:19 exhibits "nucleic acid binding activity." While the protein shares identity with other nucleic acid binding proteins, it is just as likely that the protein is a non-functional mutant. Even assuming SEQ ID NO:19 has "nucleic acid binding activity," it is noted that this "activity" encompasses a vast array of protein activities as described above. In this case, applicants' cited "guidance" fails to provide the guidance necessary for a skilled artisan to make and use all claimed polypeptides. It should be noted that the specification fails to discuss the relationship of the disclosed "domains," *i.e.,* potential phosphorylation sites or "signature sequences," with respect to the function of SEQ ID NO:19. It is also

noted that the phosphorylation sites are disclosed as being potential, not actual, phosphorylation sites. There is no evidence of record that the "domains" disclosed in Table 2 are conserved or non-conserved such that one would expect alteration of an amino acid within the domain or domains to alter or maintain the function or the claimed polypeptide. Further, the specification provides no guidance for altering amino acids outside of the disclosed "domains." With regard to the reference of Branden et al., it is noted that applicants do not dispute the examiner's cited teachings, and instead attack the reference as being general. That the teachings of Branden et al. are "general" underscores the fact that these teachings apply to protein engineering in general and are not specific to any class of proteins. It should be noted that Branden et al. do not state their teachings are limited to any particular protein and there is no evidence of record that would indicate that the teachings of Branden et al., which apply to a broad class of proteins, are not relative the claimed protein. In the absence of such evidence, the examiner maintains the teachings of Branden et al. apply to the claimed protein. Regarding the reference of Witkowski et al., applicants do not dispute the examiner's cited teachings, and instead attack the reference as being non-applicable. While it is acknowledged that the teachings of Witkowski et al. do not address a nucleic acid binding protein, these teachings exemplify the broad teachings of Branden et al. that apply to proteins in general as acknowledged by applicants. At least for the reasons of record and those stated above, the examiner maintains the position that the specification is enabling only for the polypeptide of SEQ ID NO:19 and that undue experimentation is required for a skilled artisan to make and use the full scope of

claimed polypeptides, particularly for those reasons set forth in the analysis of the Factors of *In re Wands* (see pp. 15-17 of the Office action mailed April 21, 2004).

Conclusion

[13] Status of the claims:

Claims 1-2, 8, 15, and 28-30 are pending.

Claim 29 is withdrawn from consideration.

Claims 1-2, 8, 15, 28, and 30 are rejected.

No claim is in condition for allowance.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

12-13-04
David J. Steadman, Ph.D.
Primary Examiner